EC Declaration of Conformity

We, **Kaz Europe Sàrl**, Place Chauderon 18, 1003 Lausanne, Switzerland declare under our sole responsibility that the product to which this declaration relates is in conformity with the following standard(s) or other normative document(s) and proves the conformity of the designated product with the provisions of the EC Directive(s):

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Name	Type or model
Braun No Touch + Forehead Thermometer (also named as Braun Touchless + Forehead Thermometer) NTF3000 series	NTF3000WE NTF3000EE NTF 3000 NTF3000AP NTF3000KO NTF3000AU NTF3000CN

Standards Applied:

Reference Number	Title	Date of issue
EN 60601-1	Medical electrical equipment - Part 1: General requirements for safety and essential performance.	2006 +A1:2013 +A12:2014
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2015
EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2010
EN 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2010
EN 62304	Medical device software - Software life-cycle processes	2006/AC:2008
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing	2009
EN 12470-5	Clinical thermometers - Part 5 Performance of infra-red ear thermometers (with maximum device)	2003
EN ISO 14971	Medical devices - Application of risk management to medical devices	2012
EN 980	Graphical symbols for use in the labelling of medical devices	2008
EN 1041	Information supplied by the manufacturer with medical devices	2008
ASTM E1965-98	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	2003

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Conformity assessment procedure:

Device Classification	Annex	UMDNS
IIa (Annex IX rule 10)	V	14-036

The Technical Documentation is the responsibility of: Kaz Europe Sàrl, Place Chauderon 18, CH-1003 Lausanne, Switzerland

Notified body: DQS Medizinprodukte GmbH, August Schanz Str. 21, D-60433, Frankfurt, Germany (registration number: 0297)

This declaration of conformity is valid until 2020-06-26.

Roelof Zeijpveld		Lausanne	12 December 2016
General Manager p.o. Alain Fonjallaz	Legally binding signature	Place	Date

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